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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,973	09/13/2006	Toshikazu Nakamura	2006_0825A	1561

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EXAMINER	
ALLEN, MARIANNE P	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,973	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/15/06, 1/5/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are pending and under consideration by the examiner.

Claim Objections

Claims 10, 13, 15, and 16 are objected to because of the following informalities: They refer to claim 1 twice within each claim. Applicant is reminded that multiple dependent claims should refer to multiple claims in the alternative. These claims should be amended to refer to claim 1 a single time. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-7, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 and 18-21 of copending Application No. 10/926,088. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to overlapping embodiments of glycosylation deficient HGF.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 8-9 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-8 of copending Application No. 11/041,363. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to overlapping embodiments of DNA sequences (and vectors containing said DNA) encoding glycosylation deficient HGF.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

Claims 8-10, 13, 15, 16, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 10, 13, 15, and 16 are confusing in reciting the DNA encoding the glycosylation-deficient growth factor according to claim 1. This is confusing because claim 1

has no requirement for the glycosylation deficiency to be due to the DNA sequence (see for example claim 2) rather than the method of production or post-production treatment (see for example claim 14). There is no antecedent basis for this concept in claim 1.

Claim 17 is directed to a pharmaceutical composition comprising the HGF of claim 1. This claim is confusing because it does not clearly require any additional components that would further limit the product of claim 1. These appear to be duplicate claims because they do not differ in scope.

Claim 18 is directed to a gene therapy agent comprising the DNA encoding HGF of claim 8. This claim is confusing because it does not clearly require any additional components that would further limit the product of claim 8. These appear to be duplicate claims because they do not differ in scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 5, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann et al. (of record).

Hofman discloses purification of human and canine HGF from cells treated with tunicamycin and glycosidases that would result in glycosylation deficient HGF lacking sugar chains at at least one glycosylation site.

Claims 1, 4, 10-11, 14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hara et al. (of record).

Hara et al. discloses recombinantly produced HGF treated with glycosidases that would result in glycosylation deficient HGF lacking sugar chains at at least one glycosylation site.

Claims 1-4, 6-15, and 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Godowski et al. (U.S. Patent No. 5,316,921).

Godowski et al. discloses recombinantly producing glycosylation mutants of HGF by modifying the glycosylation sites. Production in yeast, insect cells, E. coli, and mammalian cells is disclosed. Post production enzymatic treatment is also disclosed. (See at least columns 14-15.) The five amino acid deletion form of instant SEQ ID NO: 2 is disclosed. (See column 2, lines 5-10.)

Claims 1, 5, 8, 9, 10, 15, and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyake et al. (U.S. Patent No. 7,125,688).

Miyake et al. discloses DNA sequences, vectors, and methods of producing feline HGF in E. coli. Recombinant production in E. coli would result in glycosylation deficient HGF.

Pharmaceutical compositions are disclosed. See at least abstract, claims, and column 7. With respect to the gene therapy agent of claim 18, the only requirement is the DNA of claim 8.

Claims 1, 5, 8, 9, 10, 15, and 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Miyake et al. (U.S. Patent No. 7,129,064).

Miyake et al. discloses DNA sequences, vectors, and methods of producing canine HGF in E. coli. Recombinant production in E. coli would result in glycosylation deficient HGF. Pharmaceutical compositions are disclosed. See at least abstract, claims, and column 7. With respect to the gene therapy agent of claim 18, the only requirement is the DNA of claim 8.

Claims 1, 8, 9, and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Patten et al. (U.S. Patent No. 6,365,377).

Patten et al. discloses recombinantly producing a hepatocyte growth factor in a cell free system such as an E. coli lysate. The hepatocyte growth factor produced would be glycosylation deficient. See at least abstract, columns 21-23, and claims, particularly claim 24.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Friday, 5:30 am - 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

mpa